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1265439

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December 22, 2004

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APPLICATION NUMBER: *60/608,565*
FILING DATE: *September 10, 2004*
RELATED PCT APPLICATION NUMBER: *PCT/US04/39400*

Certified by

Jon W Dudas

Acting Under Secretary of Commerce
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PTO/SB/16 (04-04)
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV068780287US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
F. Mark	Ferguson	1595 E. Treeview Drive Salt Lake City, UT 84124

Additional inventors are being named on the 1 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☑ Customer Number: 26,152

OR

☐ Firm or Individual Name					
Address					
Address					
City		State		Zip	
Country		Telephone		Fax	

ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 9 ☐ CD(s), Number

☑ Drawing(s) *Number of Sheets* 21 ☑ Other (specify) Assignment

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.

☑ A check or money order is enclosed to cover the filing fees.

☑ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 19-3542

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE Amount ($): 160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME Paul S. Evans

Date September 10, 2004

REGISTRATION NO. 36,130 *(if appropriate)*

Docket Number: SHP026.4.1.1

TELEPHONE 801-298-3360

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PROVISIONAL APPLICATION COVER SHEET
Additional Page

PTO/SB/16 (04-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Docket Number SHP026.4.1.1

INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)
Jeremy W.	Snow	155 North 575 East North Salt Lake, UT 84054

Number 1 of 1

PTO/SB/17 (10-03)
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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 200.00

Complete if Known	
Application Number	
Filing Date	September 10, 2004
First Named Inventor	F. Mark FERGUSON
Examiner Name	
Art Unit	
Attorney Docket No.	SHP026.4.1.1

METHOD OF PAYMENT *(check all that apply)*

☑ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 19-3542

Deposit Account Name: Specialized Health Produc

The Director is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	160.00

SUBTOTAL (1) ($) 160.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		X	=
Independent Claims		- 3** =		X	=
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	40.00
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 40.00

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Paul S. Evans	*Registration No. (Attorney/Agent)*	36,130	*Telephone*	801-298-3360
Signature				*Date*	9/10/04

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Express Mail No. EV 068780287US

PROVISIONAL PATENT APPLICATION
Docket No: SHP026.4.1.1

CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that the enclosed Provisional Patent Application consisting of 9pages of specification, 21 sheets of drawings, and Check No.011236 For $120.00 in the matter of the Application of Specialized Health Products, Inc. for SAFETY SHIELD FOR NEEDLES; Declaration and Power of Attorney; Assignment and form PTO-1595; is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated below in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

JODI BARRUS

EV068780287US
EXPRESS MAIL LABEL NUMBER

September 10, 2004
DATE OF DEPOSIT

SAFETY SHIELD FOR MEDICAL NEEDLES

CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation-in-part of U.S. Utility Patent Application Serial No. 10/739,868, filed in the U.S. Patent and Trademark Office on December 18, 2003 by Ferguson et al., which claims priority to U.S. Utility Patent Application Serial No. 10/409,819, filed in the U.S. Patent and Trademark Office on April 8, 2003 by Ferguson et al., and U.S. Utility Application Serial No. 10/322,288, filed in the U.S. Patent and Trademark Office on December 17, 2002 by Ferguson et al., which claims priority to U.S. Provisional Patent application Serial No. 60/424,655, filed in the U.S. Patent and Trademark Office on November 7, 2002 by Bagley et al., and U.S. Utility Patent Application Serial No. 10/202,201, filed in the U.S. Patent and Trademark Office on July 23, 2002 by Ferguson et al., which is a continuation-in-part of U.S. Utility Patent Application Serial No. 09/809,357, filed in the U.S. Patent and Trademark Office on March 15, 2001 by Ferguson et al., the entire contents of each of these disclosures being hereby incorporated by reference herein.

BACKGROUND

1. Technical Field

The present disclosure generally relates to safety shields for medical needles, and more particularly, to resettable safety shields that protect a needle point of a medical needle.

2. Description of the Related Art

Problems associated with inadvertent needle sticks are well known in the art of blood sampling, percutaneous medication injection and other medical procedures involving use of medical needles. Significant attention has been focused on needle stick

problems due to the contemporary sensitivity of exposure to AIDS, Hepatitis and other serious blood-borne pathogen exposures.

Procedures for removing a needle from a patient commonly require a technician to use one hand to place pressure at the wound site where the needle is being withdrawn, while removing the needle device with the other hand. It is also common practice for an attending technician to give higher priority to care for the patient than is given to disposal of a needle. In the case of typical needle devices without safety shields, such priority either requires the convenience of an available sharps container within reach or another means for safe disposal without leaving the patient's side. Providing adequate care while following safety procedures is often compounded by the patient's physical condition and mental state, such as in burn units and psychiatric wards. Under such conditions, it is difficult to properly dispose of a used needle while caring for a patient.

The widespread knowledge and history associated with needle care and disposal problems have resulted in numerous devices for preventing accidental needle sticks. Problems of current safety devices include difficulty of use and high cost due to their complexity and number of parts.

Other known devices employ sheaths that are spring activated, telescoping, pivoting, etc. These devices, however, may disadvantageously misfire or be cumbersome to activate. Further drawbacks of current devices include high manufacturing cost due to complexity and the number of parts. Thus, these type prior art devices may not adequately and reliably shield medical needle apparatus to prevent hazardous exposure.

Consequently, there remains a need to provide a more satisfactory solution for needle safety devices by overcoming the disadvantages and drawbacks of the prior art. Therefore, it would be desirable to provide a more adequate and reliable medical needle shield apparatus that employs a safety shield slidably movable along a medical needle to prevent hazardous exposure to a needle tip. It would be advantageous to provide such a safety shield that is capable of being reset to safely allow re-use of certain needle apparatus. Such a needle shield apparatus should be easily and reliably movable to shield a needle tip of a needle cannula.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The exemplary embodiments of the medical needle shield apparatus and methods of operation disclosed are discussed in terms of medical needles for infusion of intravenous fluids, medication infusion or fluid collection, guiding of other needles, e.g., biopsy, and more particularly, in terms of needle shield apparatus employed with a needle cannula that prevent hazardous exposure to the needle tip, including, for example, inadvertent needle sticks. It is envisioned that the present disclosure, however, finds application to a wide variety of cannula needles and devices for the infusion of preventive medications, medicaments, therapeutics, etc. to a subject, such as, for example, epidural needles, spinal needles, biopsy needles, chiba needles, potts cournand needles, coaxial introducer needles, Y-sites, etc. It is also envisioned that the present disclosure may be employed for collection of body fluids and/or tissues, including those employed during procedures relating to soft tissue biopsy, bone biopsy, phlebotomy, digestive, intestinal, urinary, veterinary, etc. It is contemplated that the medical needle shield apparatus may be utilized with other medical needle applications including, but not limited to, fluid infusion, fluid collection, catheters, catheter introducers, guidewire introducers, biopsy needle introducers, spinal and epidural, biopsy, aphaeresis, dialysis, blood donor, Veress needles, Huber needles, etc.

In the discussion that follows, the term "proximal" refers to a portion of a structure that is closer to a clinician, and the term "distal" refers to a portion that is further from the clinician. As used herein, the term "subject" refers to a patient that receives infusions or has blood and/or fluid collected therefrom using the medical needle shield apparatus. According to the present disclosure, the term "clinician" refers to an individual administering an infusion, performing fluid or tissue collection, installing or removing a needle cannula from a medical needle shield apparatus and may include support personnel.

The following discussion includes a description of the medical needle shield apparatus, followed by a description of the method of operating the medical needle shield apparatus in accordance with the present disclosure. Reference will now be made in

detail to the exemplary embodiments of the disclosure, which are illustrated in the accompanying figures.

Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGURES 1-5, there is illustrated a medical needle shield apparatus, constructed in accordance with the principals of the present disclosure.

In certain applications it may be desirable to reset a locked friction based single aperture plate safety device that protects a contaminated sharp (e.g., a medical needle, stylet, etc.). In such a circumstance, it is important to maintain the safety of the sharp while allowing the reuse of the sharp. It is also important that the resetting procedure is intuitive and does not cause any major changes to current physician technique. The following invention provides a solution to reset a locked friction based single aperture plate safety device that is intuitive and allows continued safety of a contaminated sharp.

One embodiment illustrates the use of the reset element 1. This embodiment has the reset element 1 as part of the inner housing 2. The reset element 1 may be part of, but is not limited to, the following: the hub/handle 3, inner housing 2, outer housing 4, aperture plate 5, or may be a separate piece that interacts with any of the above pieces. The reset element 1 may contain reset surfaces 6 that are intended to interact with the binding member 7. When the reset element 1 is active these reset surfaces 6 interact with the binding member 7 to cause the binding on the cannula 8 to be unlocked. If the reset element 1 is a part of the binding member 7 the reset surfaces 6 can extend from the binding member 7 and can be directly linked so that the activation of the reset element 1 will unlock the binding to the cannula 8.

In order for the device to be safe, it is desirable that the reset element 1 be inactive, meaning that the device cannot be accidentally reset and cause injury. It is also desirable to design the reset element 1 such that an intentional effort must be made to activate the reset element 1 and reset the device. Therefore, it may be desirable to have the reset element 1 capable of toggling between active and inactive states. This can be accomplished in many ways which include, but are not limited to, hinges, cantilevered beams, bi-stable mechanisms, springs, etc.

In order to activate the reset element 1, an intentional effort must be made which may require the reset element 1 to interact with reset geometry 9 that has been intentionally brought into a position to reset the device. One embodiment shows reset geometry 9 on a hub/handle 10. This reset geometry 9 may include a luer on a hub/handle, a separate piece containing reset geometry, and geometry on a tray. However, the reset geometry 9 is not limited to geometry on any apparatus intended to interact with the reset element 1 to reset the device.

It may also be desirable to incorporate a retention element 11. In many cases it is desirable to have the device 12 retained in some manner until the device 12 is bound to the cannula 8. One embodiment shows the device 12 retained to a hub/handle 10. In this configuration, the device 12 is retained until the stylet is removed at which time the device senses the end of the stylet and binds to the cannula 8. This embodiment depicts the retention element 11 as a detent arrangement, which allows the device 12 to be retained to the hub/handle 10. The retention element 11 may also include, but is not limited to, a snap, latch, hook, friction, etc.

Referring to FIGURES 6-10, in certain procedures it is necessary to retain the stylet handle 21 to the main device handle 22. Previous retention elements included detents and bayonet style retention. These methods may cause abrupt forces upon removal, which can lead to device misplacement or further pain to the patient. These retention methods may also fail due to the high forces or rotational movement experienced during a procedure.

The embodiment shown in FIGURES 6-10 illustrates retention with a snap arrangement 23. This allows for a robust retention to the main device handle 22. It snaps 25 securely in place and resists rotational movement as well as axial movement. The snap arrangement 23 may also have a button/lever 26 or other similar snap arrangement to release the snap 25 engagement. This allows for no abrupt forces upon removal and an easy one-handed release.

Referring to FIGURES 11-19, in certain procedures depth stops 31 are required. They often have adjustment capabilities 32. One embodiment shows the adjustment capabilities 32 which includes, but is not being limited to, threads 34. In such instances,

the safety device 33 may contain adjustment capabilities 32 such as threads 34 to advance the depth stop 31. The safety device 33 may also have depth indicators 35 to show the current depth of a depth stop 31. The safety device 33 may also act as a retainer 36 for the depth stop 31. The retainer 36 may include, but is not limited to, detents, hooks, friction, etc. The depth stop 31 may also be a means of activating the safety device 33.

Another embodiment shows the safety device 33 which incorporates a depth stop 31 with adjustment capabilities 32. The adjustment capabilities 32 may be similar to those mentioned above. The depth stop 31 may have a retainer 36 similar to that mentioned above. The retainer 36 may also serve the function of a safety device detent as well. One embodiment also includes a lock nut 37 that can be used in conjunction with depth stop 31 and thread 34.

In certain procedures it may be necessary to introduce an apparatus 40, such as a guide wire, catheter, etc., through a cannula 38. In these circumstances it may also be desirable to activate a safety device 33 to protect the sharp 39 while the apparatus 40 remains in the cannula 38. One embodiment illustrates the use of a dual end sensing member 41. This type of end sensing member can allow full function of the device with an apparatus 40 through the cannula 38. The dual end sensing member 41 is positioned to slide along the cannula 38, thus preventing binding of the binding member 42. The dual end sensing member 41 can also be positioned to slide on the outer rim of the cannula 38. In this position, the dual end sensing member 41 still senses the end of the cannula 38. However, as the binding member 42 passes through to its binding state the dual end sensing member 41 can pass around any apparatus 40 disposed in the cannula 38.

Another application of the dual end sensing member 41 is for resetting applications. In some resetting cases, the end sensing member is lodged underneath the cannula 38. This may cause the device to not be resettable. A dual end sensing member 41 may be forced around the cannula 38 by a resetting piece 43 when being reset. The dual end sensing member 41 may be flexible enough to go around the cannula 38 when resetting is occurring, yet be rigid enough to not slip around the cannula 38 during normal use. This may require a balance of forces.

Referring to FIGURES 20-21, one embodiment shows an I-type bone biopsy product having a depth stop 53. Typical I-type bone biopsy products require a depth stop 53. They often have adjustment capabilities 52 which include, but are not limited to, threads. However, there are procedures that make use of the full needle length 55 of the device. In this case, the depth stop 53 is removed to expose a longer needle. This may create a problem in that the user is required to disassemble the product for certain procedures. The illustrated embodiment allows the full needle length 55 of the needle to be initially exposed. The required depth stop 53 may be disposed behind the initial exposed full length 55. This allows the user to perform a procedure that requires the full needle length 55 of the needle without disassembly or assembly processes. There is also no change in technique for other procedures. The depth stop 53 is still available for use with an increased range of adjustable use. This is also advantageous for safety devices. Because there is no assembly or disassembly required, there is less chance that a user will inadvertently activate the safety device while removing the depth stop 53 to access the full needle length 55.

The invention of the present disclosure may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A medical needle shield apparatus comprising:

a shield slidably movable along a medical needle from a proximal position where a distal end of the needle is exposed, to a distal position where the shield protects the distal end of the needle, said shield comprising:

a binding member having an aperture through which the needle passes, said aperture having binding surfaces;

a retainer integral with the binding member and in communication with the needle for temporarily retaining the binding surfaces in a non-binding position relative to the needle; and

a positioning member including a friction element configured to engage the medical needle and generate a drag force to cause orientation of the binding member for positioning the binding surfaces to secure the shield to the needle when a portion of the retainer in contact with the needle is advanced past the distal end of the needle and allows the retainer to release from the needle and move out of an axial path defined by the needle.

ABSTRACT OF THE DISCLOSURE

A medical needle shield apparatus is provided that includes a needle hub having an outer needle cannula extending therefrom. An inner needle is disposed for slidable movement with the outer needle cannula. At least one shield is extensible from a retracted position to an extended position to enclose a distal end of the inner needle. The shield includes a binding member disposed within the shield and defines binding surfaces that form an aperture configured for slidable receipt of the inner needle.

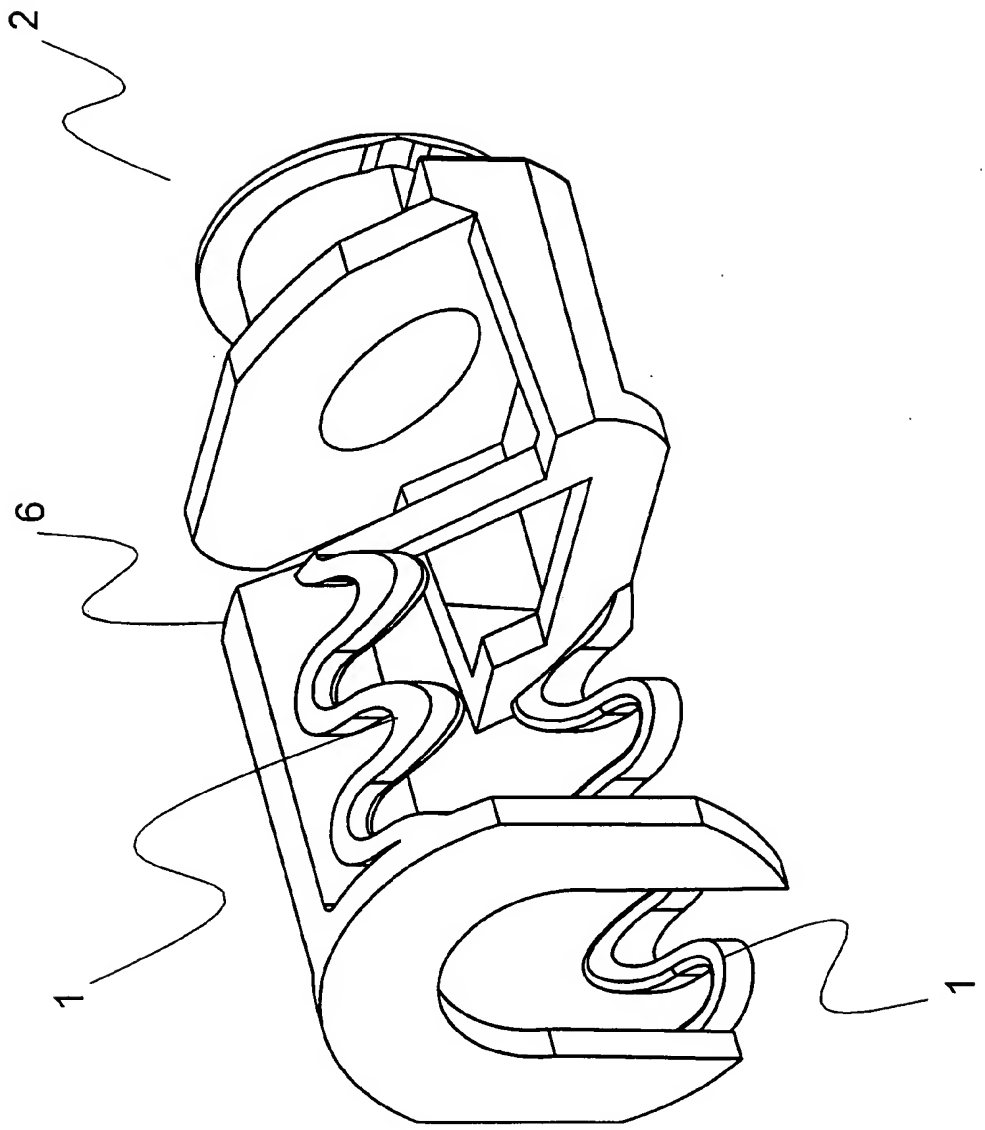

FIGURE 1

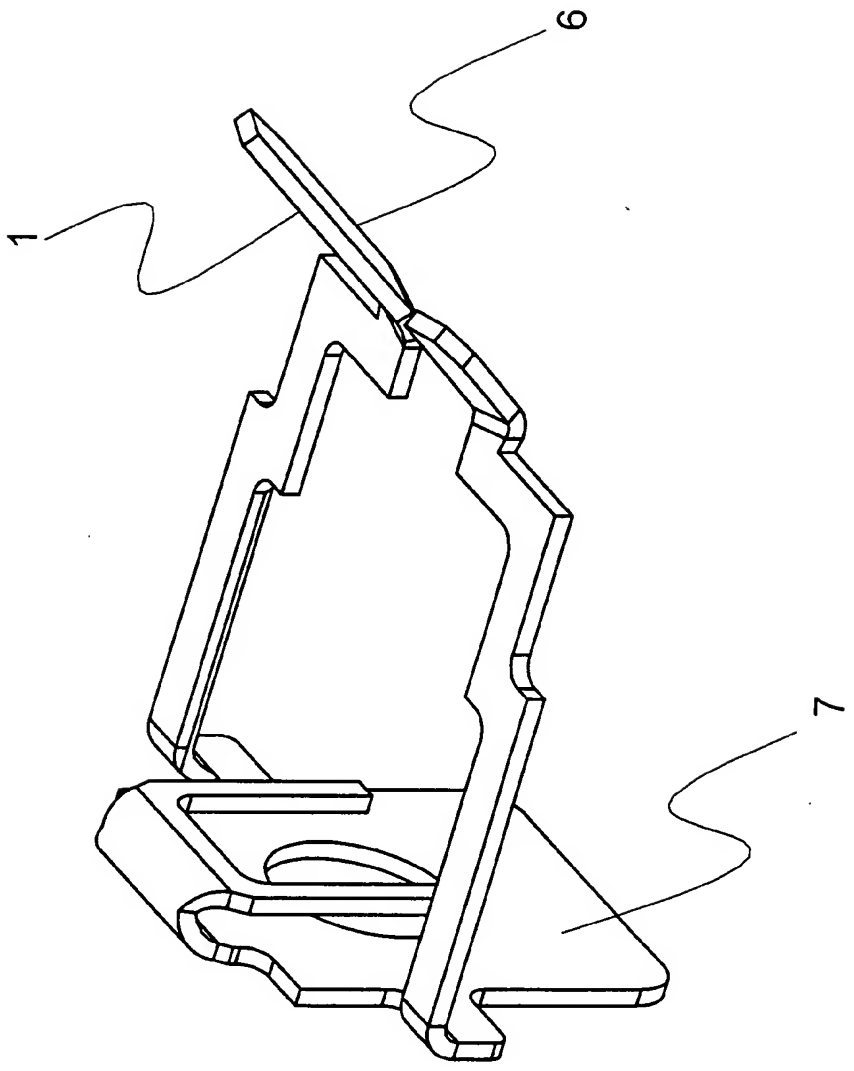

FIGURE 2

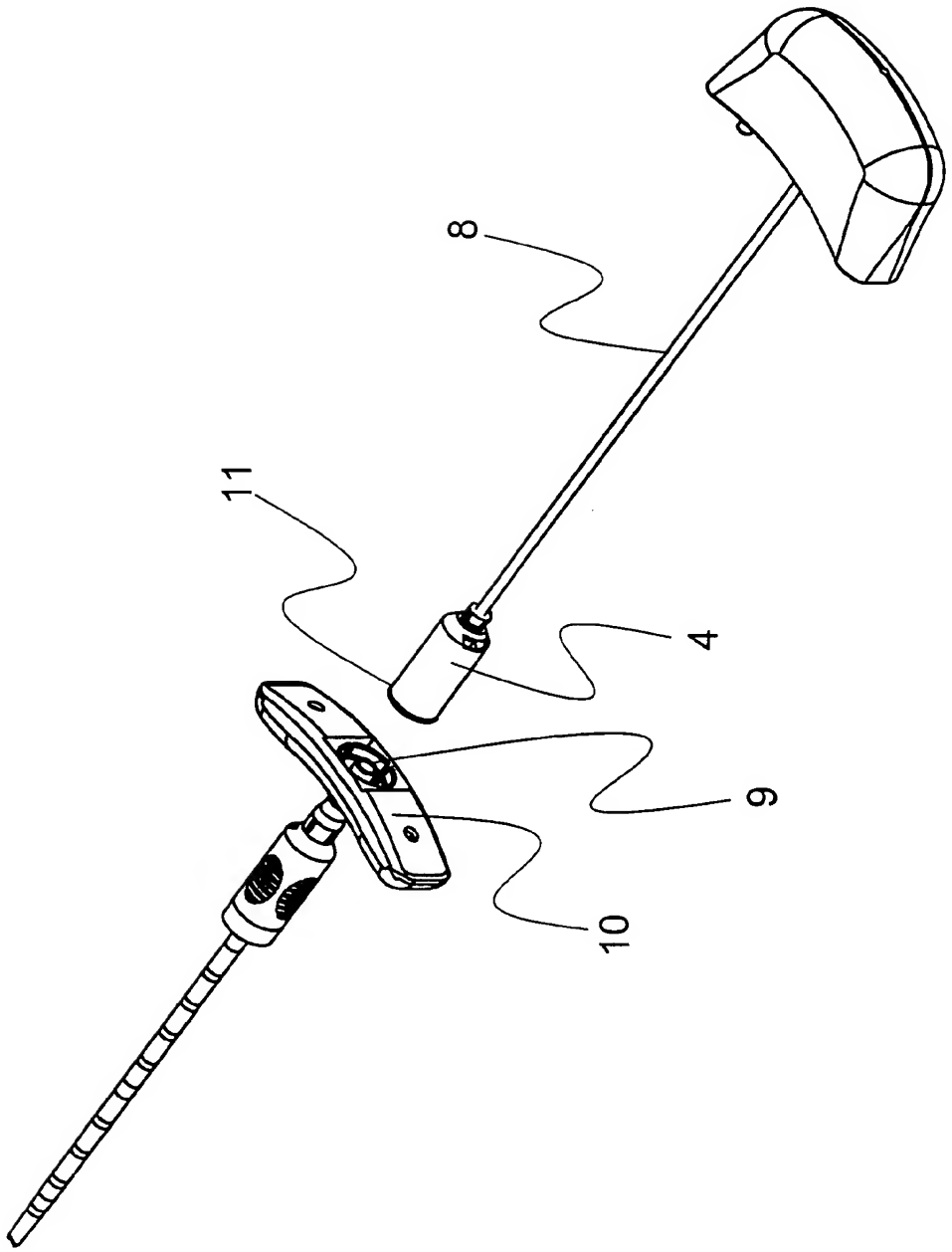

FIGURE 3

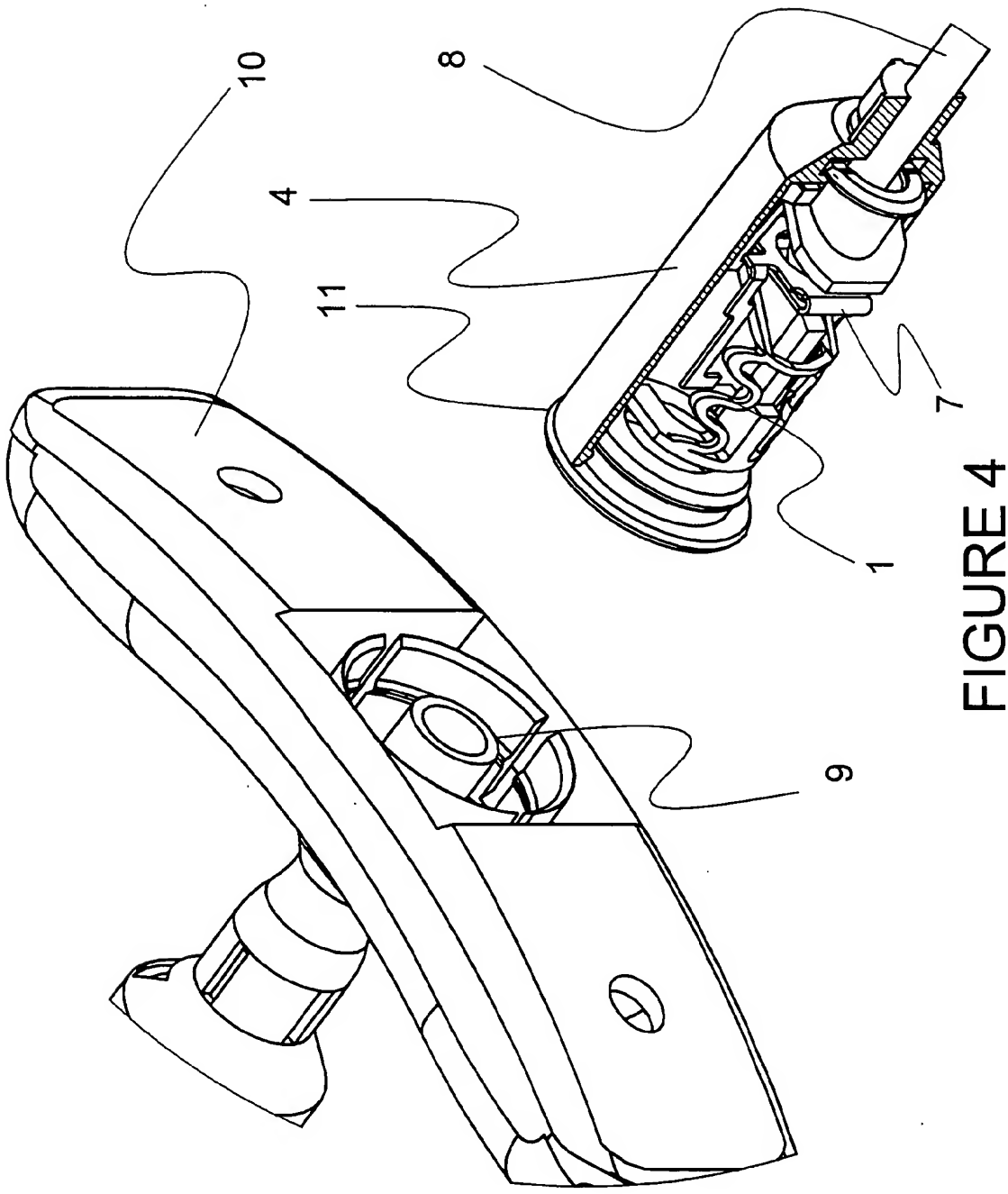

FIGURE 4

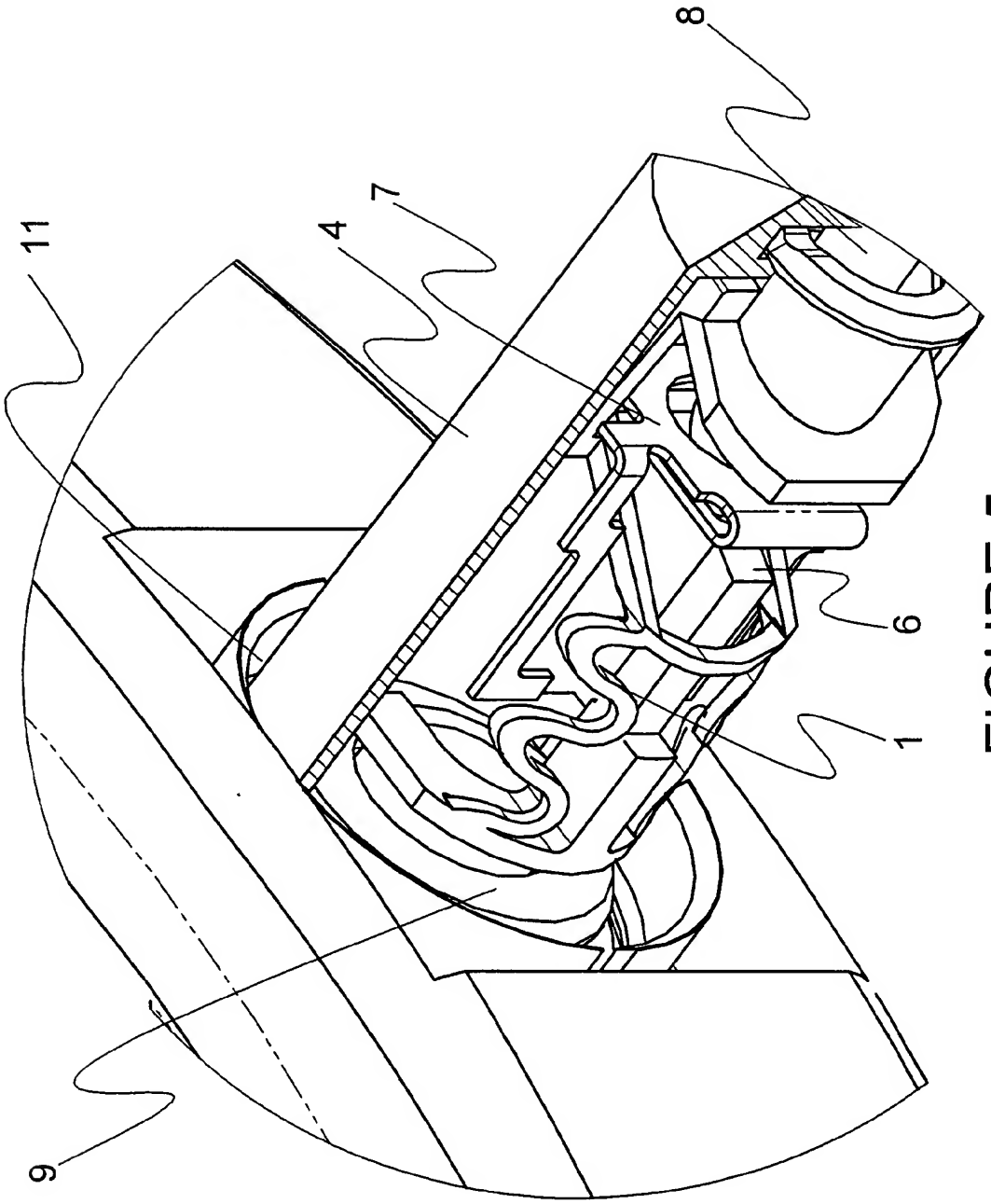

FIGURE 5

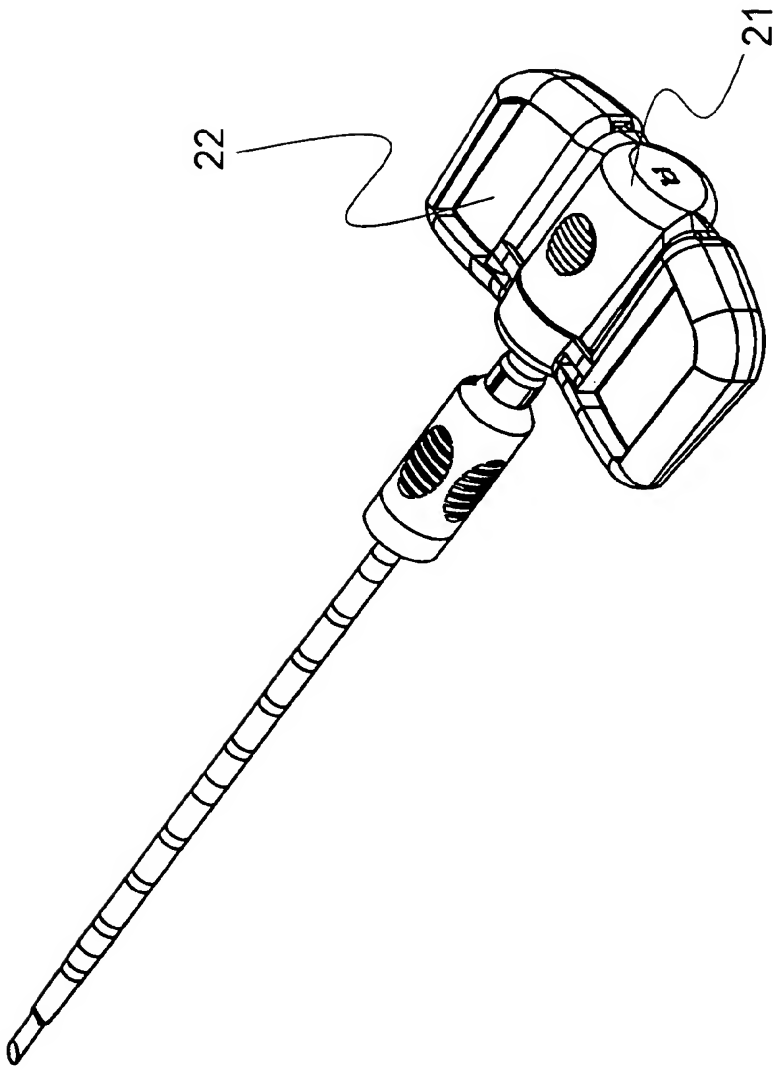

FIGURE 6

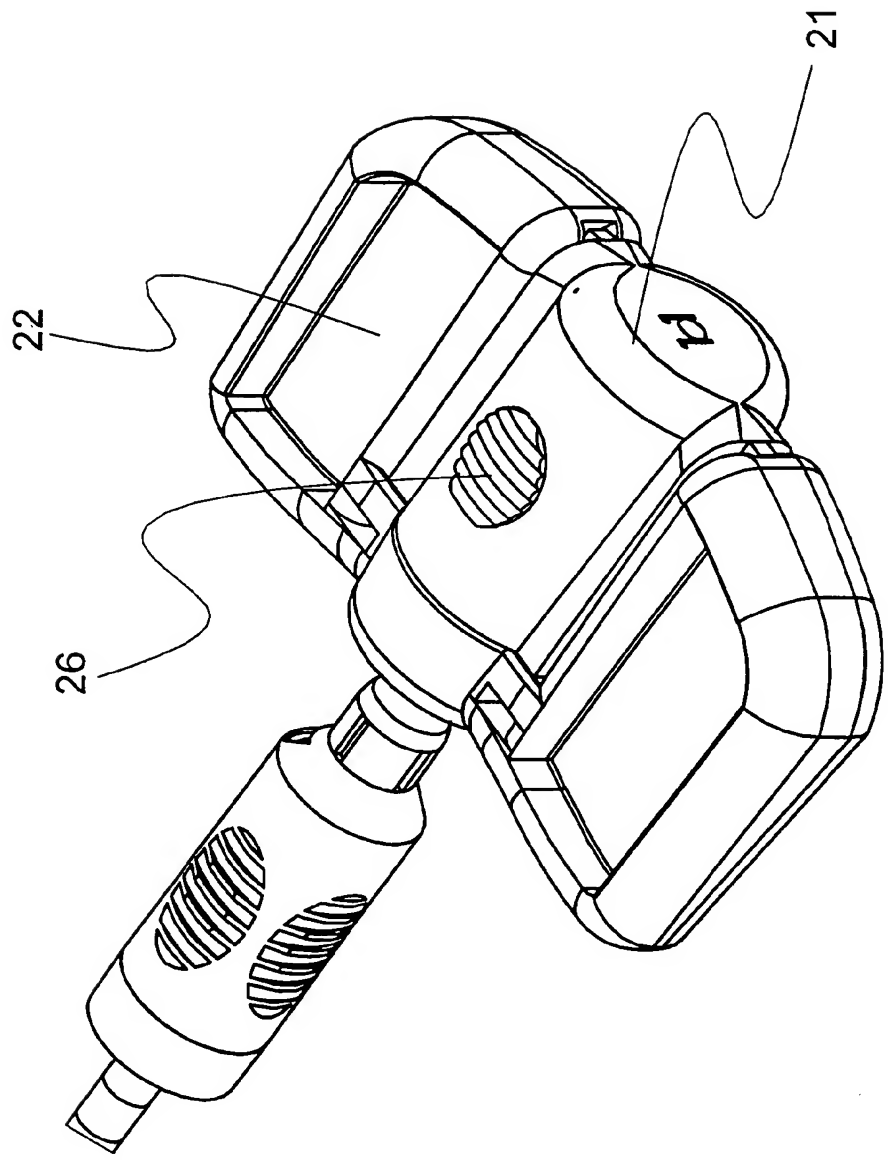

FIGURE 7

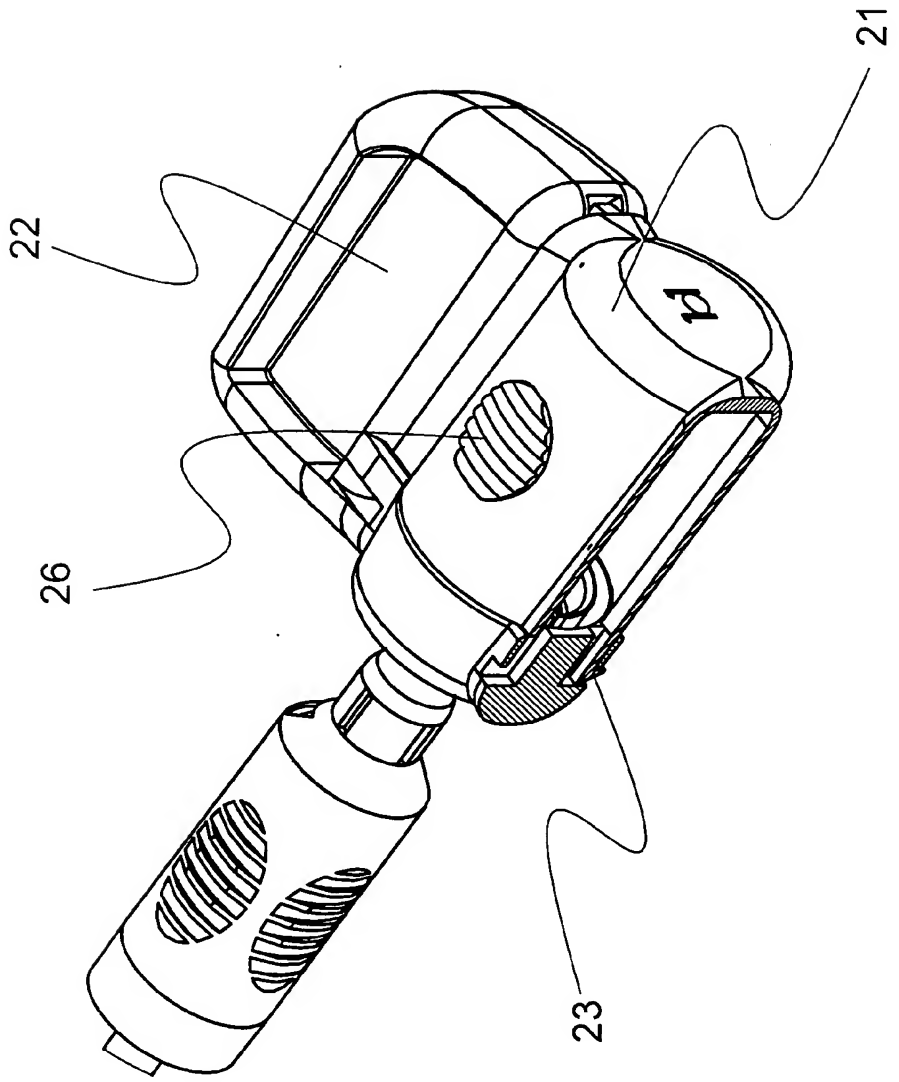

FIGURE 8

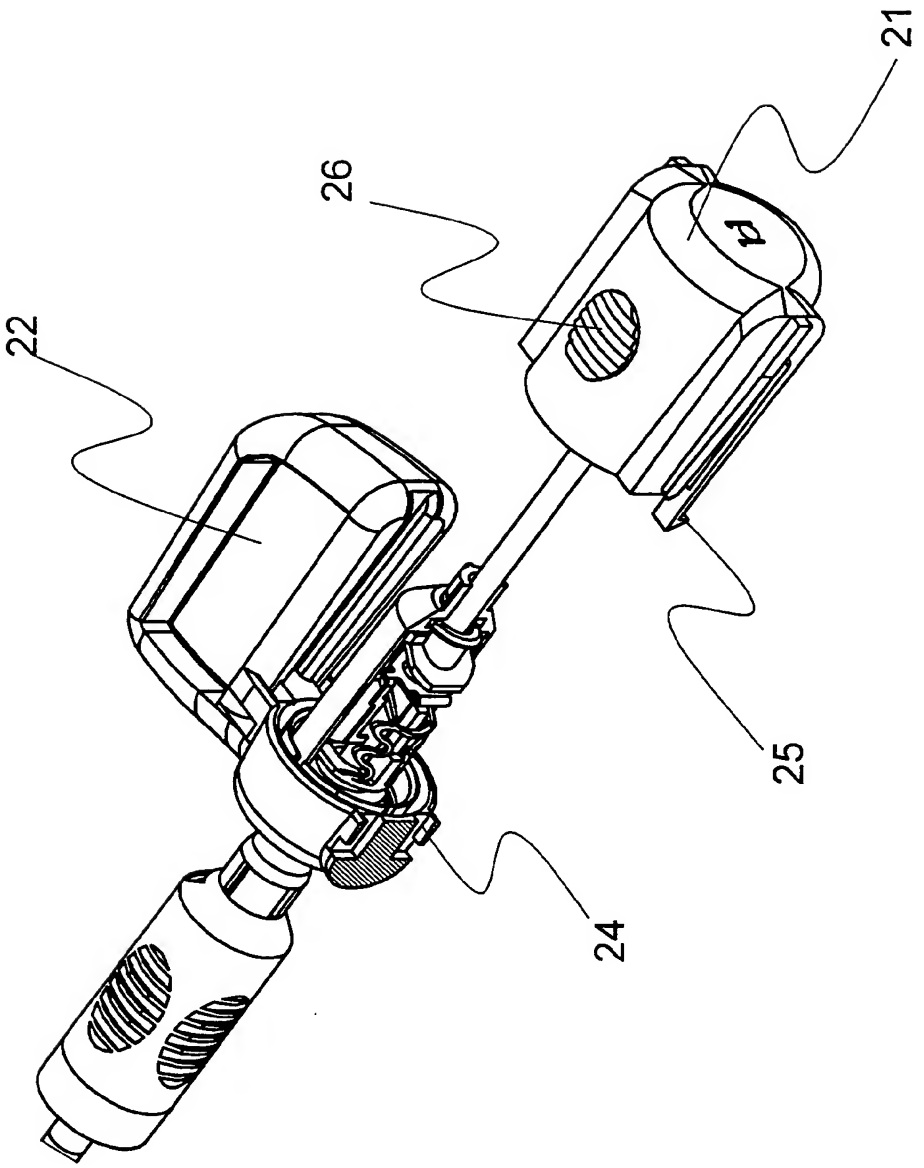

FIGURE 9

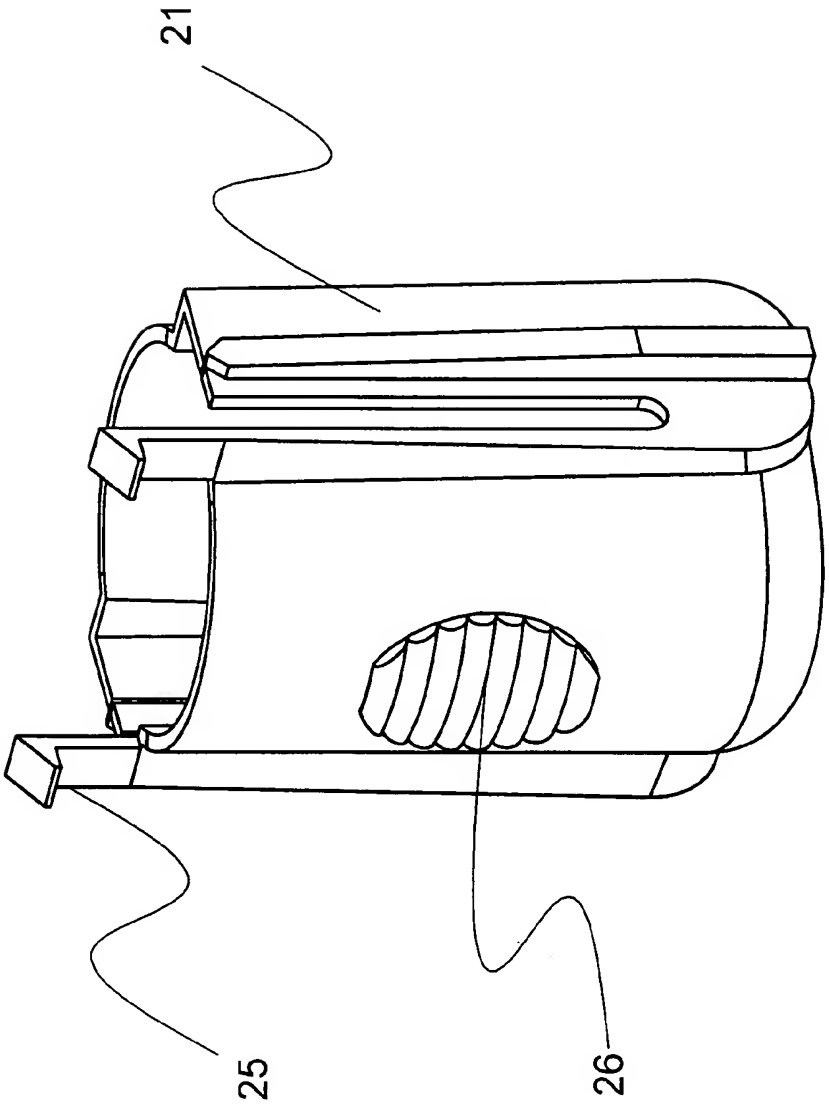

FIGURE 10

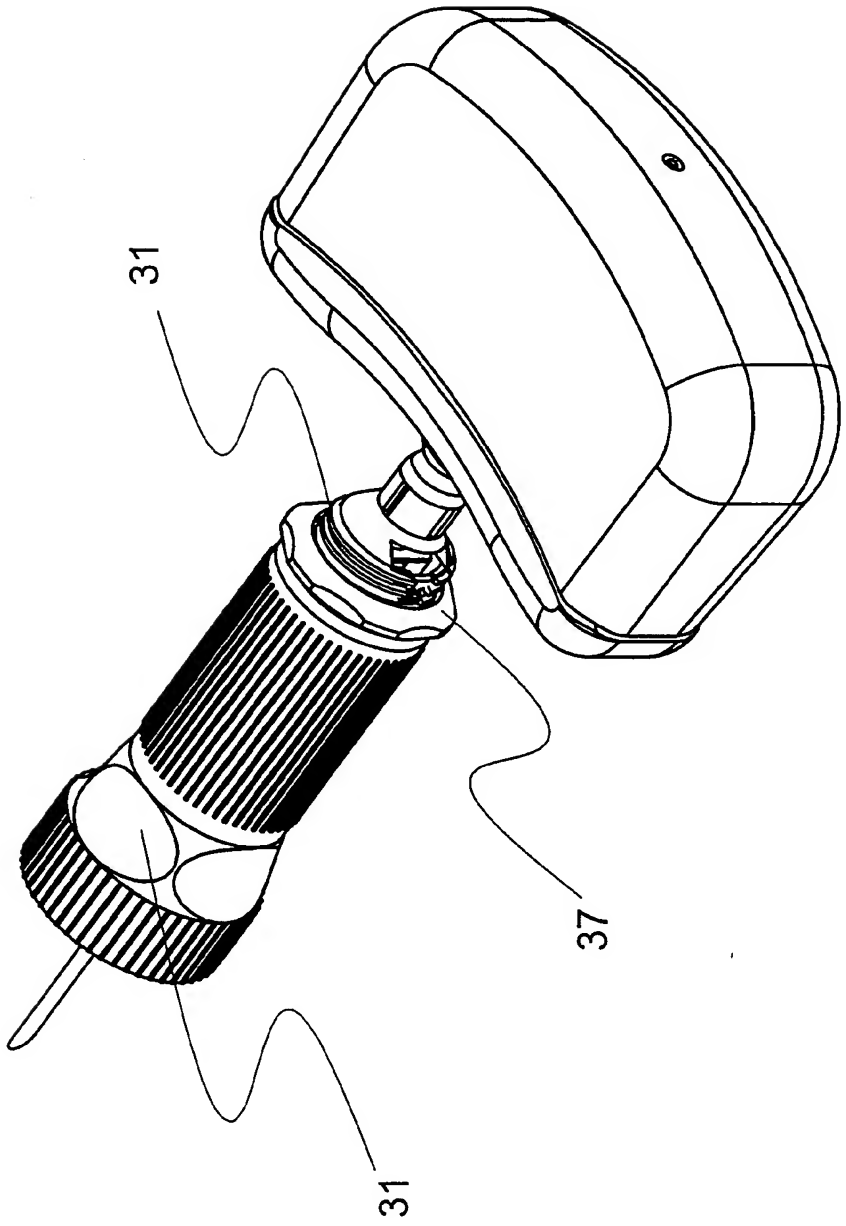

FIGURE 11

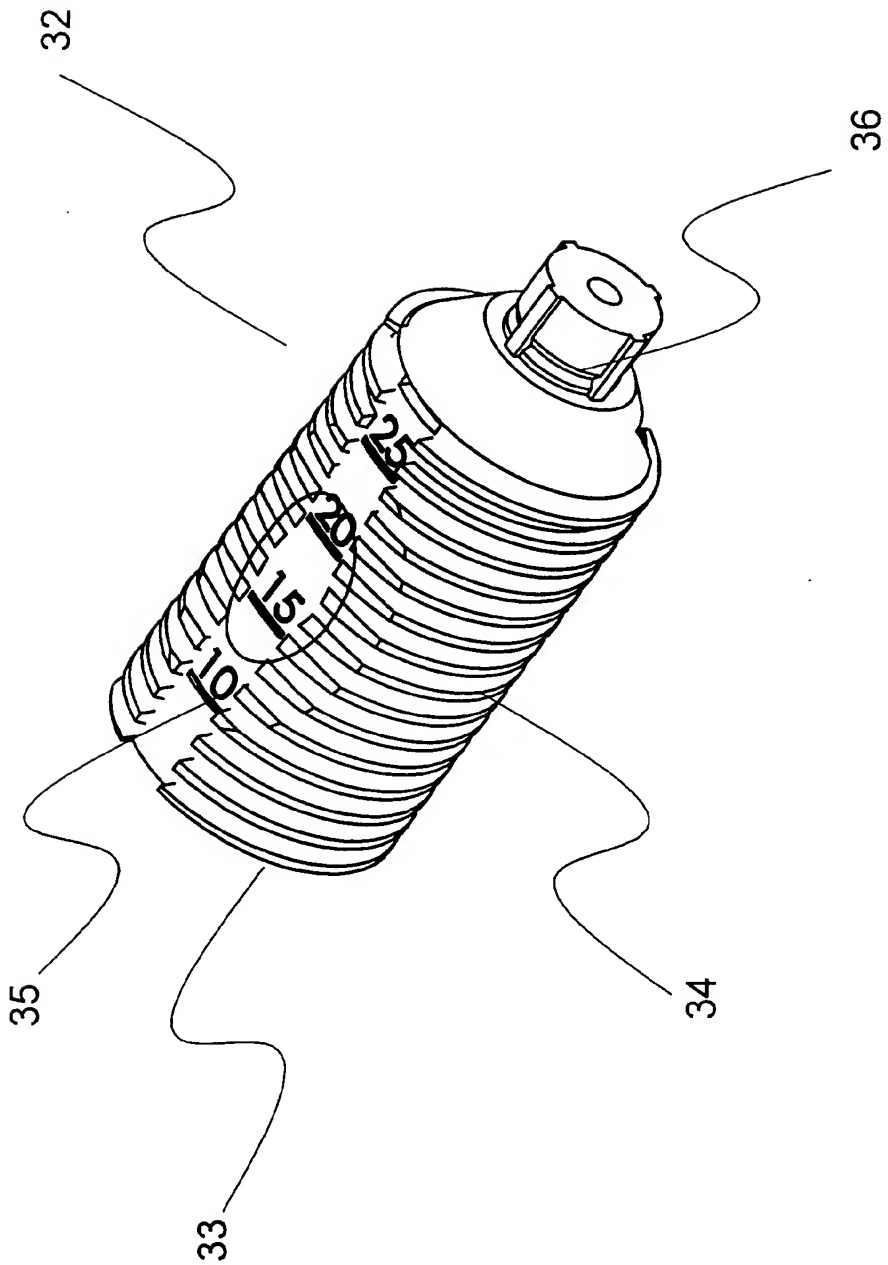

FIGURE 12

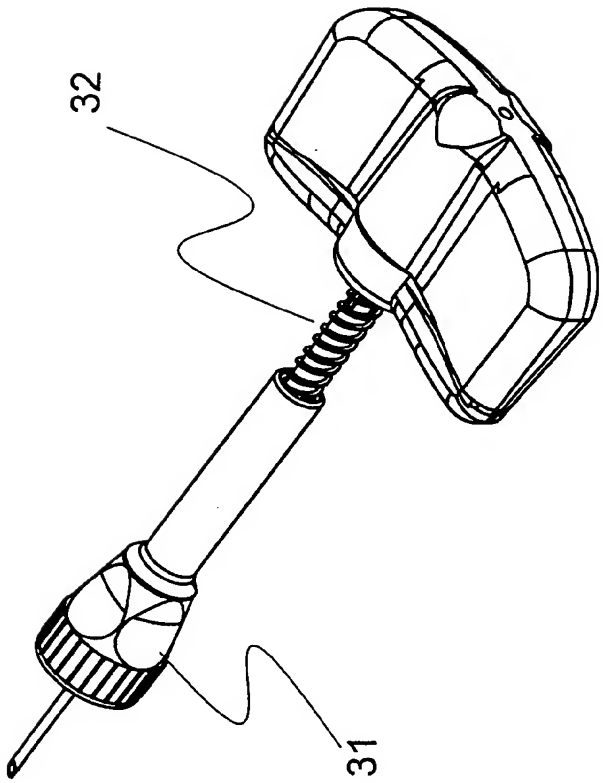

FIGURE 13

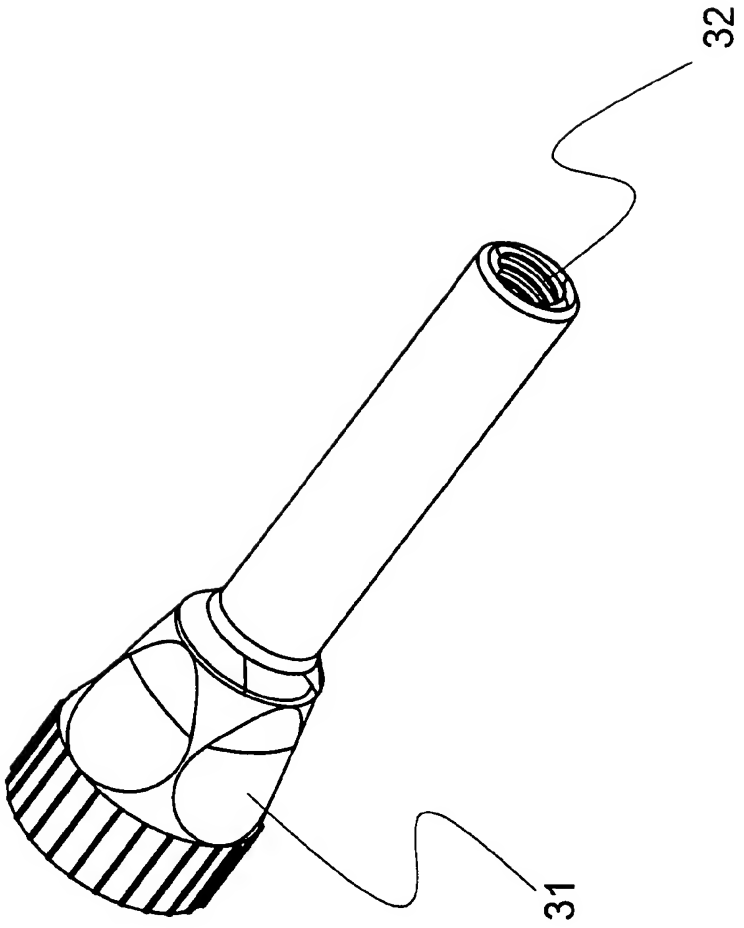

FIGURE 14

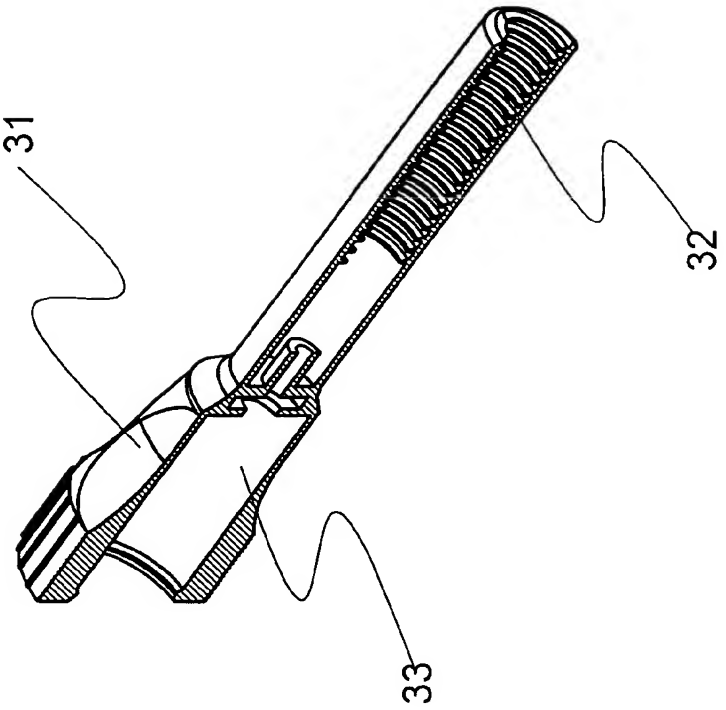

FIGURE 15

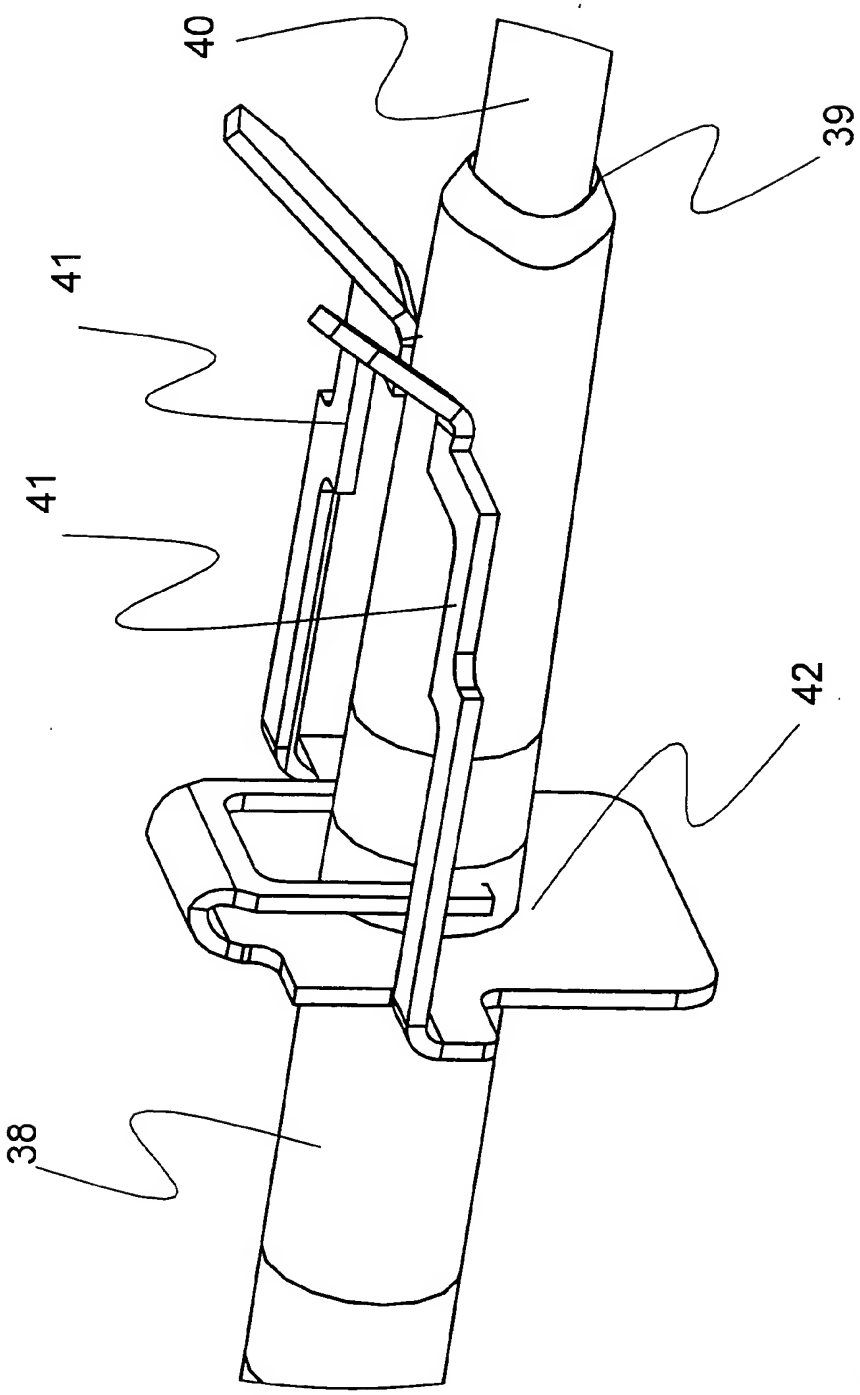

FIGURE 16

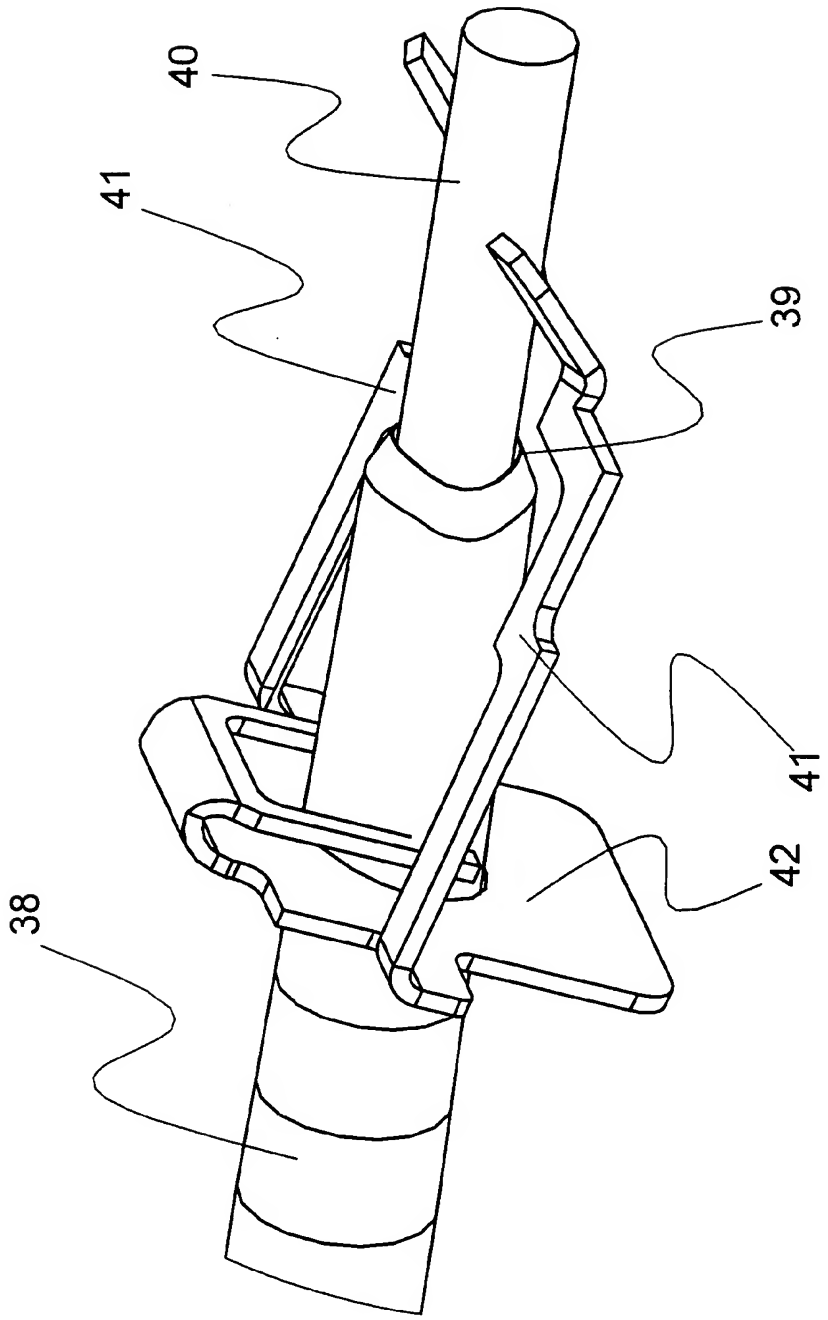

FIGURE 17

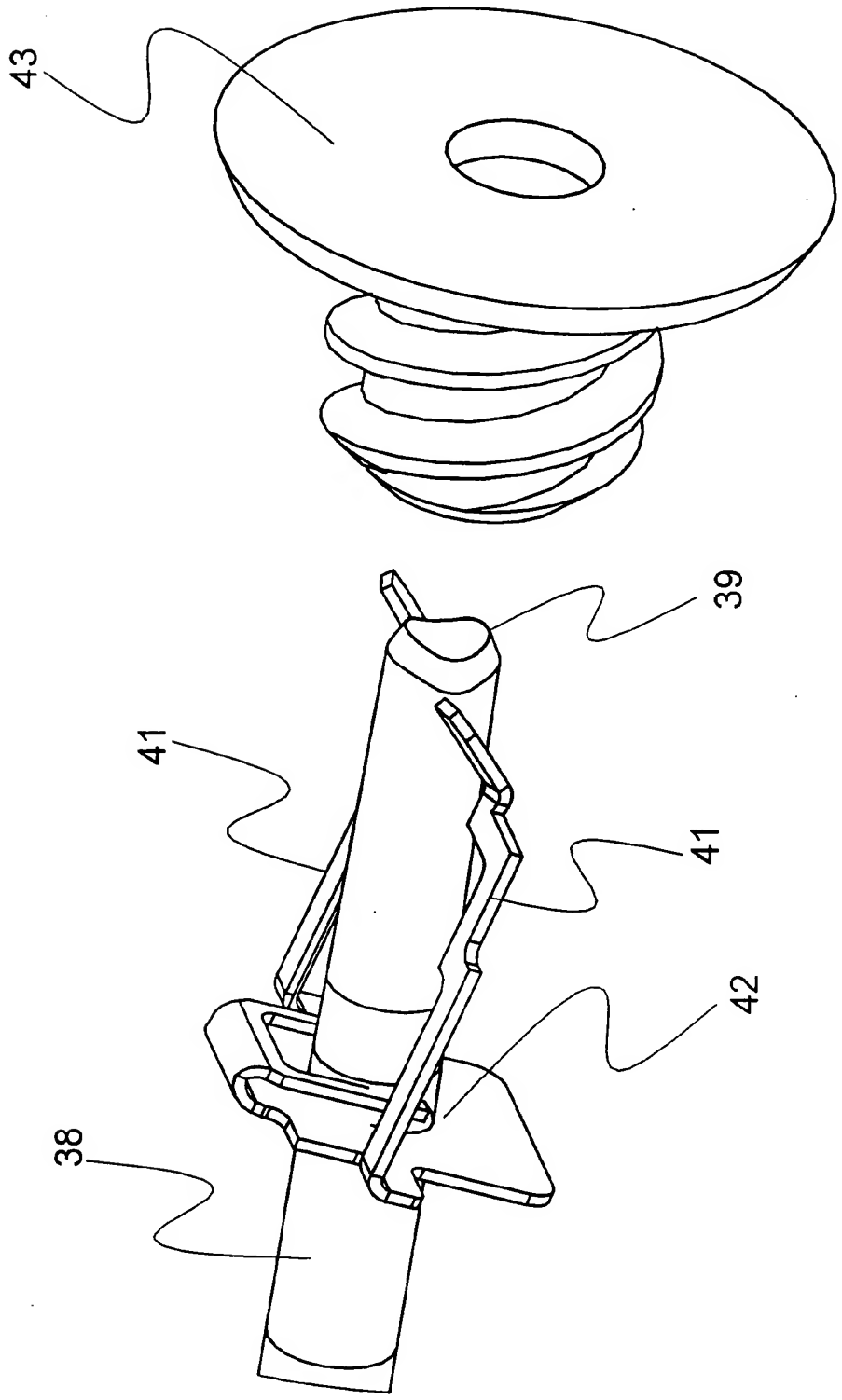

FIGURE 18

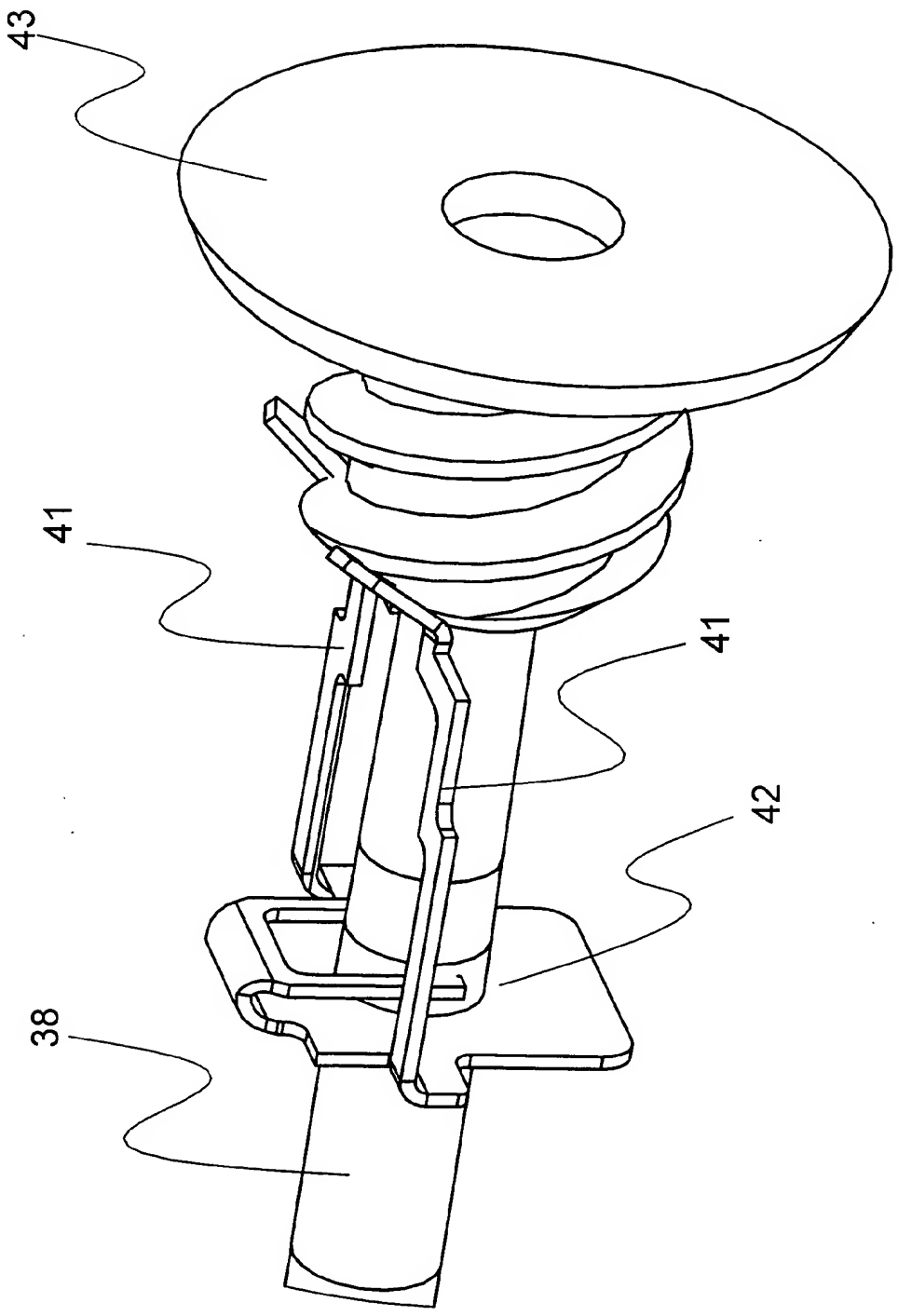

FIGURE 19

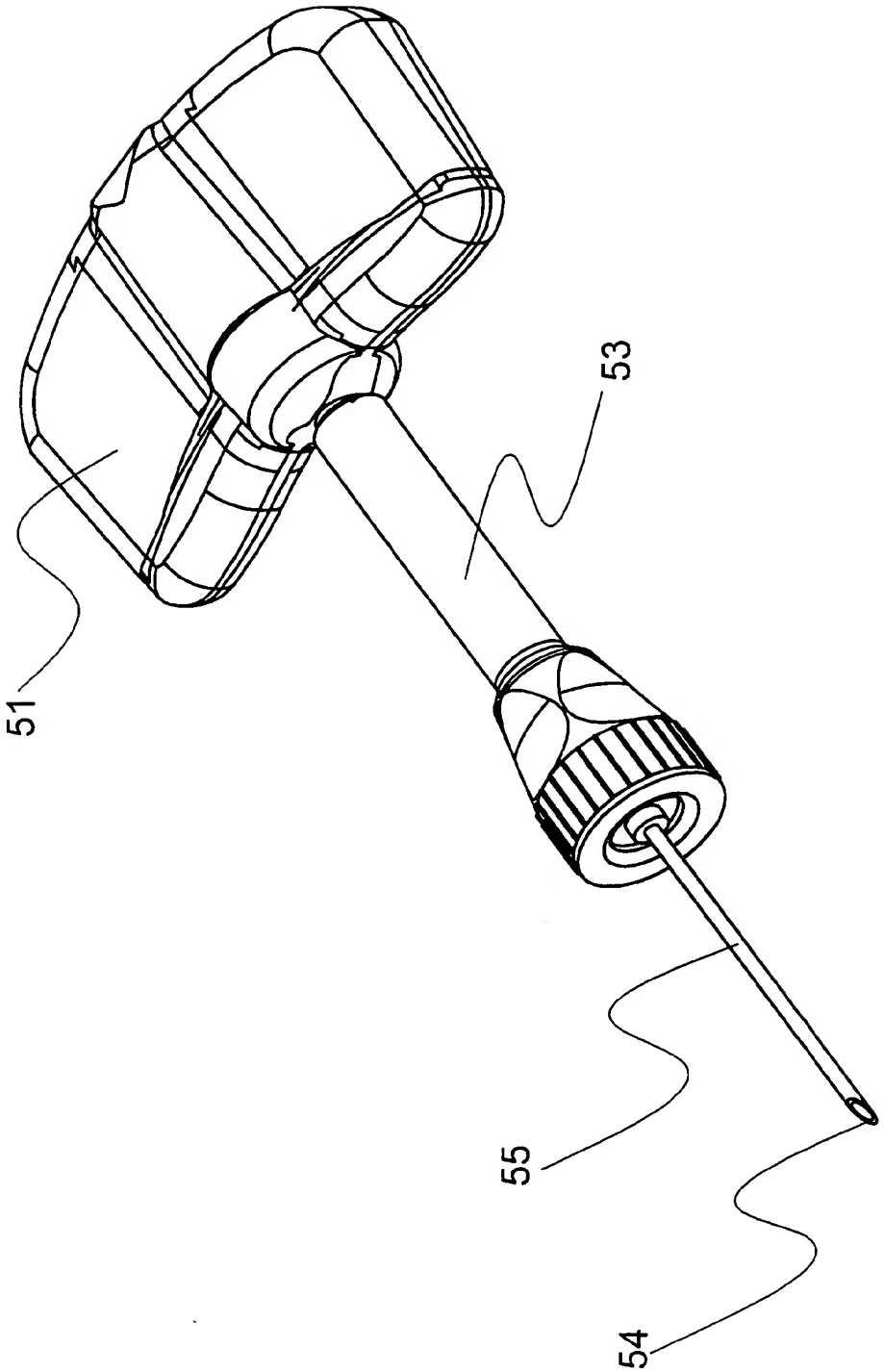

FIGURE 20

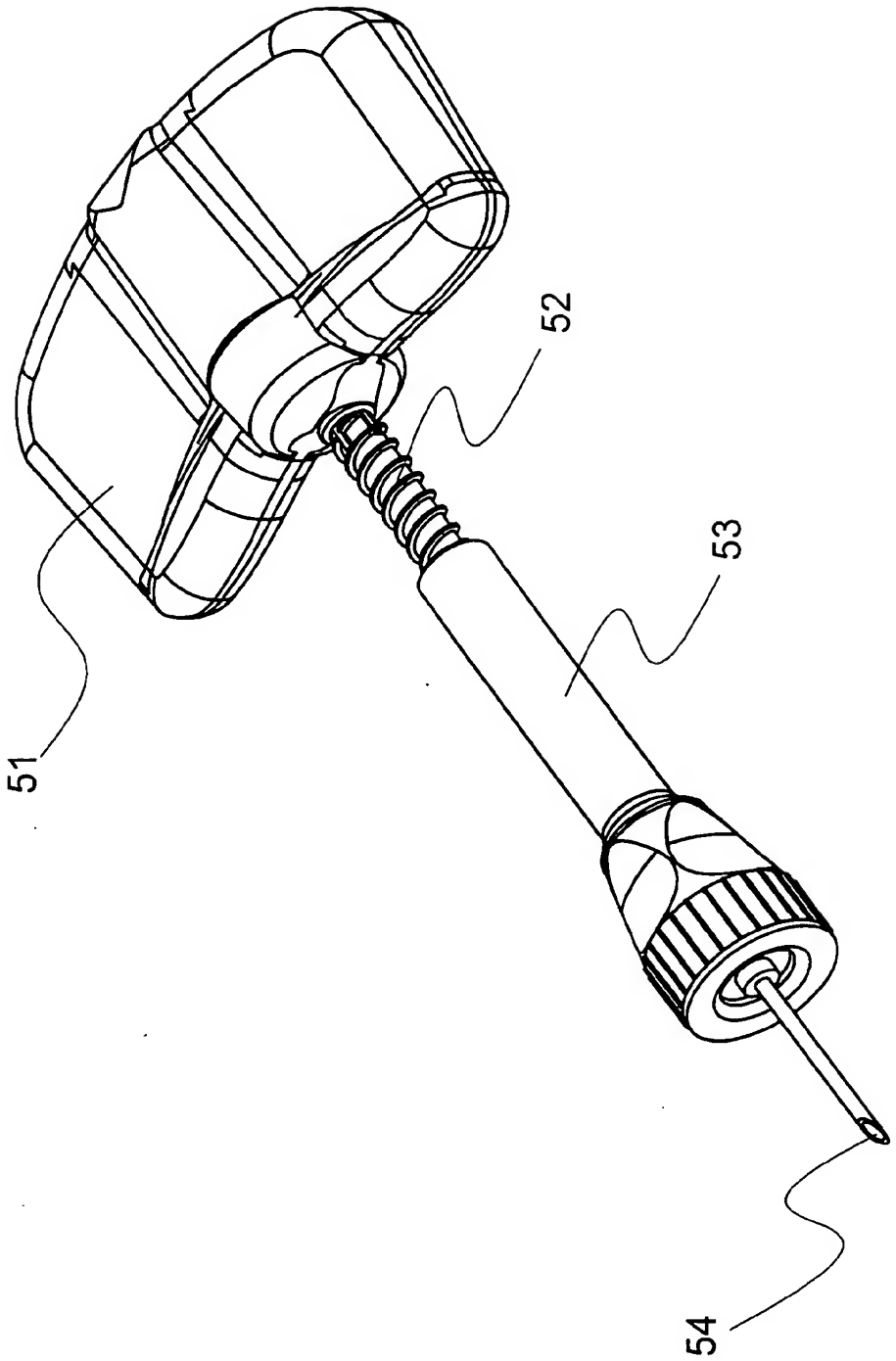

FIGURE 21

Docket No. SHP026.4.1.1

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor(s), I hereby declare that:

TYPE OF DECLARATION

This declaration is for a **PROVISIONAL** patent application.

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if two or more names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

SAFETY SHIELD FOR MEDICAL NEEDLES

SPECIFICATION IDENTIFICATION

The specification

☒ is attached hereto.

☐ was filed on and has U.S. Application Number ,
and was amended on .

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

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